APPENDIX A

REDACTED CLAIMS INDICATING AMENDMENTS MADE (37 C.F.R. §1.121(C)(ii)

Please amend claims 51-54 as follows:

— 51. (Amended) A method for treating a patient suffering from a condition, disease or disorder that is responsive to treatment with a bronchodilator/corticosteroid combination, comprising administering to the patient, via inhalation, a pharmaceutical formulation for pulmonary drug administration, wherein the formulation comprises:

a therapeutically effective amount of a bronchodilator; and

a therapeutically effective amount of a corticosteroid selected from the group consisting of mometasone and pharmacologically acceptable salts, esters and derivatives thereof~~; and~~

~~optionally, a pharmaceutically acceptable carrier suitable for pulmonary drug administration~~.

— 52. (Amended) The method of claim 51, wherein the formulation is administered via oral inhalation.

— 53. (Amended) The method of claim 51, wherein the formulation is administered via nasal inhalation.

— 54. (Amended) The method of claim 51, wherein the ~~composition is administered only as needed to treat the patient suffering from the condition, disease or disorder~~ formulation is administered on an as-needed basis.

Please add the following new claims:

— ✓ 75. (New) The method of claim 51, wherein the bronchodilator has agonist activity for β_2 adrenergic receptors.

A2

— ✓ 76. (New) The method of claim 51, wherein the bronchodilator is selected from the group consisting of albuterol, bitolterol, clenbuterol, fenoterol, formoterol, levalbuterol, metaproterenol, pirbuterol, procaterol, reproterol, rimiterol, salmeterol, terbutaline, derivatives thereof, pharmacologically acceptable salts and esters thereof, and combinations of any of the foregoing.

77. (New) The method of claim 76, wherein the bronchodilator is selected from the group consisting of pirbuterol, levalbuterol, metaproterenol, derivatives thereof, pharmacologically acceptable salts and esters thereof, and combinations of any of the foregoing.

78. (New) The method of claim 77, wherein the bronchodilator is pirbuterol or a pharmacologically acceptable salt thereof.

79. (New) The method of claim 78, wherein the bronchodilator is pirbuterol acetate.

80. (New) The method of claim 78, wherein the bronchodilator is pirbuterol dihydrochloride.

81. (New) The method of claim 77, wherein the bronchodilator is levalbuterol or a pharmacologically acceptable salt thereof.

82. (New) The method of claim 81, wherein the bronchodilator is levalbuterol sulfate.

83. (New) The method of claim 81, wherein the bronchodilator is levalbuterol hydrochloride.

84. (New) The method of claim 51, wherein the corticosteroid is selected from the group consisting of mometasone and pharmacologically acceptable esters thereof, in either anhydrous or hydrate form.

85. (New) The method of claim 84, wherein the corticosteroid is anhydrous mometasone furoate.

86. (New) The method of claim 84, wherein the corticosteroid is mometasone furoate monohydrate.

87. (New) The method of claim 51, wherein the formulation further includes a pharmaceutically acceptable carrier suitable for pulmonary drug administration.

85. (New) The method of claim 51, wherein the formulation is in the form of a dry powder.

89. (New) The method of claim 87, wherein the formulation is in the form of a dry powder.

90. (New) The method of claim 89, wherein the carrier is selected from the group consisting of fructose, galactose, glucose, lactitol, lactose, maltitol, maltose, mannitol, melezitose, myoinositol, palatinite, raffinose, stachyose, sucrose, trehalose, xylitol, hydrates thereof, and combinations of any of the foregoing.

91. (New) The method of claim 90, wherein the carrier is lactose.

92. (New) The method of claim 89, wherein the corticosteroid is anhydrous mometasone furoate.

A2

93. (New) The method of claim 87, wherein the formulation is in the form of an aerosol composition.

94. (New) The method of claim 93, wherein the carrier is a propellant.

95. (New) The method of claim 94, wherein the propellant is a hydrocarbon or a halogenated hydrocarbon.

96. (New) The method of claim 94, wherein the propellant is selected from the group consisting of 1,2-dichloro-1,1,2,2-tetrafluoroethane, 1,1-dichloro-1,2,2,2-tetrafluoroethane, trichlorofluoromethane, dichlorodifluoromethane, chloropentafluoroethane, chlorodifluoromethane, chlorodifluoroethanes, 1,1-difluoroethane, 1,2-difluoroethane, 1,1,2,2-tetrafluoroethane, 1,1,1,2-tetrafluoroethane, hexafluoroethane, octafluoropropane, 1,1,1,2,3,3,3-heptafluoropropane, octafluorocyclobutane, propane, isobutane, *n*-butane, dimethyl ether, and mixtures thereof.

97. (New) The method of claim 96, wherein the propellant is selected from the group consisting of 1,1-difluoroethane, 1,2-difluoroethane, difluoroethane, 1,1,2,2-tetrafluoroethane, 1,1,1,2-tetrafluoroethane, hexafluoroethane, octafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane, octafluorocyclobutane, and mixtures thereof.

98. (New) The method of claim 93, wherein the aerosol composition is in the form of a liquid.

99. (New) The method of claim 98, wherein the formulation comprises an aqueous suspension of the bronchodilator and the corticosteroid.

100. (New) The method of claim 98, wherein the liquid is a sodium chloride solution.

101. (New) The method of claim 98, wherein the corticosteroid is mometasone furoate monohydrate.

102. (New) The method of claim 51, wherein the formulation is in a unit dosage form.

103. (New) The method of claim 102, wherein the unit dosage form is a capsule.

104. (New) The method of claim 102, wherein unit dosage form is a unit dose vial.

105. (New) The method of claim 51, wherein the therapeutically effective amount of the bronchodilator is in the range of about 1 μg to about 1500 μg.

106. (New) The method of claim 105, wherein the therapeutically effective amount of the bronchodilator is in the range of about 50 μg to about 1300 μg.

107. (New) The method of claim 106, wherein the therapeutically effective amount of the bronchodilator is in the range of about 2.5 μg to about 350 μg.

108. (New) The method of claim 107, wherein the therapeutically effective amount of the bronchodilator is in the range of about 5.0 μg to about 150 μg.

109. (New) The method of claim 51, wherein the therapeutically effective amount of the corticosteroid is in the range of about 1 μg to about 1500 μg.

110. (New) The method of claim 105, wherein the therapeutically effective amount of the corticosteroid is in the range of about 1 μg to about 1500 μg.

111. (New) The method of claim 87, wherein the pharmaceutical formulation for pulmonary drug administration, comprises:

a therapeutically effective amount of a bronchodilator selected from the group consisting of levalbuterol sulfate, pirbuterol acetate and pirbuterol dihydrochloride;

a therapeutically effective amount of a corticosteroid selected from the group consisting of anhydrous mometasone furoate and mometasone furoate monohydrate; and

lactose.

112. (New) The method of claim 51, wherein the formulation is administered using a pulmonary drug delivery device comprising a means for housing and dispensing unit dosages of the formulation.

113. (New) The method of claim 112, wherein the pulmonary drug delivery device is a dry powder inhaler, metered-dose inhaler, nebulizer or pump spray bottle.

A2

114. (New) The method of claim 113, wherein the pulmonary drug delivery device is a dry powder inhaler.

115. (New) A method for treating a patient suffering from a condition, disease or disorder that is responsive to treatment with a bronchodilator/corticosteroid combination, comprising administering to the patient a pharmaceutical formulation for pulmonary drug administration, wherein the formulation is administered using a dry powder inhaler for orienting and positioning a capsule containing the pharmaceutical formulation to be administered, wherein the dry powder inhaler comprises:

a dispensing chamber containing a capsule of a dry powder pharmaceutical formulation comprised of a therapeutically effective amount of a bronchodilator, a therapeutically effective amount of a corticosteroid selected from the group consisting of mometasone and pharmacologically acceptable salts, esters and derivatives thereof, and a pharmaceutically acceptable carrier suitable for pulmonary drug administration;

a tube for receiving the capsule to be oriented and dispensed;

a ramp surface extending substantially across the tube from one wall to an opposite wall thereof; and

an elongate dispensing passage having a diameter less than that of the tube and sized to receive the capsule only when the elongate axis of the capsule is generally parallel to the axis of the passage, the passage extending from an inlet end formed by an aperture in the ramp's surface to a dispensing outlet, the passage being adjacent to one wall of the tube such that the axis of the passage is parallel to, but radially offset from, an axis of the tube,

whereby when the inhaler is positioned with the passage below the tube and the axis of the passage is substantially vertical, a capsule located in the tube is guided by the ramp surface towards the inlet end of the passage.

A2

116. (New) The method of claim 115, wherein the bronchodilator is selected from the group consisting of pirbuterol acetate, pirbuterol dihydrochloride, levalbuterol sulfate, and levalbuterol hydrochloride.

APPENDIX B

PENDING CLAIMS UPON ENTRY OF THIS AMENDMENT

51. A method for treating a patient suffering from a condition, disease or disorder that is responsive to treatment with a bronchodilator/corticosteroid combination, comprising administering to the patient, via inhalation, a pharmaceutical formulation for pulmonary drug administration, wherein the formulation comprises:

a therapeutically effective amount of a bronchodilator; and

a therapeutically effective amount of a corticosteroid selected from the group consisting of mometasone and pharmacologically acceptable salts, esters and derivatives thereof.

52. The method of claim 51, wherein the formulation is administered via oral inhalation.

53. The method of claim 51, wherein the formulation is administered via nasal inhalation.

54. The method of claim 51, wherein the formulation is administered on an as-needed basis.

55. The method of claim 51, wherein the condition, disease or disorder is selected from the group consisting of asthma, exercise-induced asthma, bronchitis, bronchospasm, rhinitis and emphysema.

75. The method of claim 51, wherein the bronchodilator has agonist activity for β_2 adrenergic receptors.

76. The method of claim 51, wherein the bronchodilator is selected from the group consisting of albuterol, bitolterol, clenbuterol, fenoterol, formoterol, levalbuterol, metaproterenol, pirbuterol, procaterol, reproterol, rimiterol, salmeterol, terbutaline, derivatives thereof, pharmacologically acceptable salts and esters thereof, and combinations of any of the foregoing.

77. The method of claim 76, wherein the bronchodilator is selected from the group consisting of pirbuterol, levalbuterol, metaproterenol, derivatives thereof, pharmacologically acceptable salts and esters thereof, and combinations of any of the foregoing.

78. The method of claim 77, wherein the bronchodilator is pirbuterol or a pharmacologically acceptable salt thereof.

79. The method of claim 78, wherein the bronchodilator is pirbuterol acetate.

80. The method of claim 78, wherein the bronchodilator is pirbuterol dihydrochloride.

81. The method of claim 77, wherein the bronchodilator is levalbuterol or a pharmacologically acceptable salt thereof.

82. The method of claim 81, wherein the bronchodilator is levalbuterol sulfate.

83. The method of claim 81, wherein the bronchodilator is levalbuterol hydrochloride.

84. The method of claim 51, wherein the corticosteroid is selected from the group consisting of mometasone and pharmacologically acceptable esters thereof, in either anhydrous or hydrate form.

85. The method of claim 84, wherein the corticosteroid is anhydrous mometasone furoate.

86. The method of claim 84, wherein the corticosteroid is mometasone furoate monohydrate.

87. The method of claim 51, wherein the formulation further includes a pharmaceutically acceptable carrier suitable for pulmonary drug administration.

85. The method of claim 51, wherein the formulation is in the form of a dry powder.

89. The method of claim 87, wherein the formulation is in the form of a dry powder.

90. The method of claim 89, wherein the carrier is selected from the group consisting of fructose, galactose, glucose, lactitol, lactose, maltitol, maltose, mannitol, melezitose, myoinositol, palatinite, raffinose, stachyose, sucrose, trehalose, xylitol, hydrates thereof, and combinations of any of the foregoing.

91. The method of claim 90, wherein the carrier is lactose.

92. The method of claim 89, wherein the corticosteroid is anhydrous mometasone furoate.

93. The method of claim 87, wherein the formulation is in the form of an aerosol composition.

94. The method of claim 93, wherein the carrier is a propellant.

95. The method of claim 94, wherein the propellant is a hydrocarbon or a halogenated hydrocarbon.

96. The method of claim 94, wherein the propellant is selected from the group consisting of 1,2-dichloro-1,1,2,2-tetrafluoroethane, 1,1-dichloro-1,2,2,2-tetrafluoroethane, trichlorofluoromethane, dichlorodifluoromethane, chloropentafluoroethane, chlorodifluoromethane, chlorodifluoroethanes, 1,1-difluoroethane, 1,2-difluoroethane, 1,1,2,2-tetrafluoroethane, 1,1,1,2-tetrafluoroethane, hexafluoroethane, octafluoropropane, 1,1,1,2,3,3,3-heptafluoropropane, octafluorocyclobutane, propane, isobutane, *n*-butane, dimethyl ether, and mixtures thereof.

97. The method of claim 96, wherein the propellant is selected from the group consisting of 1,1-difluoroethane, 1,2-difluoroethane, difluoroethane, 1,1,2,2-tetrafluoroethane, 1,1,1,2-tetrafluoroethane, hexafluoroethane, octafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane, octafluorocyclobutane, and mixtures thereof.

98. The method of claim 93, wherein the aerosol composition is in the form of a liquid.

99. The method of claim 98, wherein the formulation comprises an aqueous suspension of the bronchodilator and the corticosteroid.

100. The method of claim 98, wherein the liquid is a sodium chloride solution.

101. The method of claim 98, wherein the corticosteroid is mometasone furoate monohydrate.

102. The method of claim 51, wherein the formulation is in a unit dosage form.

103. The method of claim 102, wherein the unit dosage form is a capsule.

104. The method of claim 102, wherein unit dosage form is a unit dose vial.

105. The method of claim 51, wherein the therapeutically effective amount of the bronchodilator is in the range of about 1 μg to about 1500 μg.

106. The method of claim 105, wherein the therapeutically effective amount of the bronchodilator is in the range of about 50 μg to about 1300 μg.

107. The method of claim 106, wherein the therapeutically effective amount of the bronchodilator is in the range of about 2.5 μg to about 350 μg.

108. The method of claim 107, wherein the therapeutically effective amount of the bronchodilator is in the range of about 5.0 μg to about 150 μg.

109. The method of claim 51, wherein the therapeutically effective amount of the corticosteroid is in the range of about 1 μg to about 1500 μg.

110. The method of claim 105, wherein the therapeutically effective amount of the corticosteroid is in the range of about 1 μg to about 1500 μg.

111. The method of claim 87, wherein the pharmaceutical formulation for pulmonary drug administration comprises:

a therapeutically effective amount of a bronchodilator selected from the group consisting of levalbuterol sulfate, pirbuterol acetate and pirbuterol dihydrochloride;

a therapeutically effective amount of a corticosteroid selected from the group consisting of anhydrous mometasone furoate and mometasone furoate monohydrate; and

lactose.

112. The method of claim 51, wherein the formulation is administered using a pulmonary drug delivery device comprising a means for housing and dispensing unit dosages of the formulation.

113. The method of claim 112, wherein the pulmonary drug delivery device is a dry powder inhaler, metered-dose inhaler, nebulizer or pump spray bottle.

114. The method of claim 113, wherein the pulmonary drug delivery device is a dry powder inhaler.

115. A method for treating a patient suffering from a condition, disease or disorder that is responsive to treatment with a bronchodilator/corticosteroid combination, comprising administering to the patient a pharmaceutical formulation for pulmonary drug administration, wherein the formulation is administered using a dry powder inhaler for orienting and positioning a capsule containing the pharmaceutical formulation to be administered, wherein the dry powder inhaler comprises:

a dispensing chamber containing a capsule of a dry powder pharmaceutical formulation comprised of a therapeutically effective amount of a bronchodilator, a therapeutically effective amount of a corticosteroid selected from the group consisting of mometasone and pharmacologically acceptable salts, esters and derivatives thereof, and a pharmaceutically acceptable carrier suitable for pulmonary drug administration;

a tube for receiving the capsule to be oriented and dispensed;

a ramp surface extending substantially across the tube from one wall to an opposite wall thereof; and

an elongate dispensing passage having a diameter less than that of the tube and sized to receive the capsule only when the elongate axis of the capsule is generally parallel to the axis of the passage, the passage extending from an inlet end formed by an aperture in the ramp's surface to a dispensing outlet, the passage being adjacent to one wall of the tube such that the axis of the passage is parallel to, but radially offset from, an axis of the tube,

whereby when the inhaler is positioned with the passage below the tube and the axis of the passage is substantially vertical, a capsule located in the tube is guided by the ramp surface towards the inlet end of the passage.

116. The method of claim 115, wherein the bronchodilator is selected from the group consisting of pirbuterol acetate, pirbuterol dihydrochloride, levalbuterol sulfate, and levalbuterol hydrochloride.